



BOSTON SCIENTIFIC CORPORATION

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Boston Scientific Corporation

- 3rd Largest Medical Device Company
 - \$8 billion in Sales
- Europe/Middle East & Africa Region
 - Present in 40 countries
 - Headquarters in Paris
 - \$2 billion in Sales



Corporate Governance Process in a US Multinational in Europe

- Sarbanes-Oxley Act of 2002
 - Section 302
- EUCOMED code of conduct
 - Interaction with physicians- congress
 - Sponsorships of institutions



Sarbanes-Oxley Act of 2002

- Known as the 'Public Company Accounting Reform and Investor Protection Act', set new or enhanced standards for all U.S. public company boards.
- Enacted as a reaction to a number of major corporate and accounting scandals like Enron.
- Section 302, requires that the company's "principal officers" (typically the CEO and CFO certify and approve the integrity of their company financial reports quarterly.



Sox 302 Quarterly Review Questionnaire

- The accurate completion of this Quarterly Review Questionnaire is a significant procedure in enabling BSC to certify the completeness of disclosures within its consolidated financial statements to the Securities and Exchange Commission (“SEC”) and to perform its review of the Company’s disclosure controls and procedures.



Sox 302 Quarterly Review Questionnaire

Compliance with BSC Accounting Policies

The Company maintains a global set of Accounting Policies which are based upon accounting principles generally accepted in the United States. Each Controller/Finance Director is responsible for ensuring compliance with BSC's Accounting Policies, including recent updates.

Comment:

The following changes in accounting treatment were made in Q2:

Increased Latitude deferral period due to the latest engineer estimates that show an increase in our battery lives. The change was implemented in June 2011 resulting in an addition \$0.8M of LDR booked in June and estimated impact on FY11 sales of \$2.7M.

Sox 302 Quarterly Review Questionnaire

Have any significant contingent liabilities, [litigation developments](#), product liability claims, or other commitments arisen subsequent to the end of the most recent reporting period which could have a [material effect](#) on your Area's financial statements or financial forecasts?

Comment:

Terminated agent_– CLOSED

- BSC agent -in Sept 2010 a letter to the agent to terminate contract for lack of performance. A \$0.4M liability was booked to cover potential severance claims , based on past experience.
- BSC offered an initial compensation of \$0.25M for the termination of the agreement, which was rejected by the agent. The offer was increased to \$0.44M, reflecting the amount Finance calculated as BSC exposure.
- A final agreement was reached on the termination terms \$443k.

Sox 302 Quarterly Review Questionnaire

Violations or potential violations of BSC's [Code of Conduct](#) or policies regarding interactions with Health Care Providers (HCPs) that may have an [impact on our Area's financial statements](#).

Comment:

Country X – (PENDING CLOSURE)

- The owner of an ex-distributor made allegations via email to Legal concerning the business practices of our current distributor. This ex-distributor was terminated in December 2008 for non-performance reasons. The allegations made against the current distributor included improper payments to HCPs as inducements for business.
- The BSC Middle East Controller interviewed the ex-distributor on March 30 2010, who reiterated the previous allegations. CA&C and Legal initiated an investigation. CA&C audited the distributor in September 2010 and found no evidence of wrongdoing.
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My thoughts on Sox

Waste of time internally because things are covered by audit procedures currently and departments such as legal and others.

Costly to maintain this process for companies

USA listings have decreased since 2002 dramatically.



Eucomed Code of Conduct

- Due to an ever growing number of scandals involving conflict of interest in the field of Medical devices involving industry and doctors.
 - Siemens fined \$1.6b
 - Johnson & Johnson \$70m
- Financial risk of infringement of the Foreign Corrupt Practices Act (FCPA).
- Medical device companies in the past 10 years have adapted rules and governance of behavior when engaging with doctors and other decision makers in the sale of products.



Eucomed Code of Conduct

- What did companies do to reduce risk
- Process our company has engaged in through the industry association called Eucomed
- How we ensure compliance with Eucomed guidelines and hence FCPA guidelines.



Eucomed Code of Conduct

- Wrote common rules applicable to all Medical Device companies in Europe and members of the Association.
 - Congress site selection and hotels
 - Sponsorship of health care professionals
- Boston Scientific included these rules into company policy
- Communicated these rules to customers
- Implemented a robust control process in the company to ensure compliance.



Eucomed Code of Conduct

- BSC has monthly meeting to govern donations and sponsorship to institutions
- Requests for congress sponsorship need sign off
- Events at congresses need sign off



Eucomed Code of Conduct

- Eucomed has a process for dispute resolution and handling complaints of breaking the rules
- Quarterly Eucomed meetings to discuss compliance



My thoughts on Compliance

- Support ensuring all companies have a level playing field, same rules for everyone
- Focus \$\$ and investment on education and not nice hotels in nice places for doctors.
- This process is a good investment of time.
- Rules usually go overboard thanks to influence from USA



Final thoughts on Corporate Governance

- Ensure there is a robust independent process in place
- Make the process simple, fast and transparent
- Starts from the TOP of the company and goes down
- Differentiate between governance of legal matters and policy matters
- Ensure everyone knows the rules and consequences of breaking the rules.